1. PRODUCT AND COMPANY IDENTIFICATION

Company

Arkema Inc.
900 First Avenue
King of Prussia, Pennsylvania 19406

Functional Additives

Customer Service Telephone Number: (800) 331-7654
(Monday through Friday, 8:00 AM to 5:00 PM EST)

Emergency Information

Transportation: CHEMTREC: (800) 424-9300
(24 hrs., 7 days a week)
Medical: Rocky Mountain Poison Center: (866) 767-5089
(24 hrs., 7 days a week)

Product Information

Product name: LUPEROX® 331MO50
Synonyms: Not available
Molecular formula: Mixture
Chemical family: Organic peroxide - peroxyketals
Product use: Polymerization inhibitor

2. HAZARDS IDENTIFICATION

Emergency Overview
Color: colourless
Physical state: liquid
Odor: Slightly aromatic

***Classification of the substance or mixture:**
Organic peroxides, Type D, H242
Skin sensitisation, Category 1, H317
Chronic aquatic toxicity, Category 4, H413

*For the full text of the H-Statements mentioned in this Section, see Section 16.

GHS-Labelling

Hazard pictograms:

Signal word: **Danger**

Hazard statements:

H242 : Heating may cause a fire.
H317 : May cause an allergic skin reaction.
H413 : May cause long lasting harmful effects to aquatic life.

Supplemental Hazard Statements:

Organic peroxide. Hazardous decomposition may occur.

Precautionary statements:

Prevention:

P210 : Keep away from heat/sparks/open flames/hot surfaces. No smoking.
P220 : Keep/Store away from clothing/ combustible materials.
P234 : Keep only in original container.
P261 : Avoid breathing gas/mist/vapours/spray.
P272 : Contaminated work clothing should not be allowed out of the workplace.
P273 : Avoid release to the environment.
P280 : Wear protective gloves/ eye protection/ face protection.

Response:

P302 + P352 : IF ON SKIN: Wash with plenty of soap and water.
P333 + P313 : If skin irritation or rash occurs: Get medical advice/ attention.
P363 : Wash contaminated clothing before reuse.

Storage:

P410 : Protect from sunlight.
P411 + P235 : Store at temperatures not exceeding .? °C/ .? °F. Keep cool.
P420 : Store away from other materials.

Disposal:

P501 : Dispose of contents/ container to an approved waste disposal plant.

Supplemental information:

Potential Health Effects:

If swallowed: Due to the viscosity, this substance may present an aspiration hazard. Prolonged or repeated skin contact may cause defatting resulting in drying, redness and rash. Symptoms of aspiration may include increased breathing and heart rate, coughing and related signs of respiratory distress.
May also cause: chest discomfort, accumulation of fluid in the lungs, (severity of effects depends on extent of exposure).

3. COMPOSITION/INFORMATION ON INGREDIENTS

Chemical Name	CAS-No.	Wt/Wt	GHS Classification**
White mineral oil (petroleum)	8042-47-5	50 %	Not classified
Peroxide, cyclohexylidenebis[(1,1-dimethylethyl)	3006-86-8	50 %	H241, H413
Hydroperoxide, 1,1-dimethylethyl	75-91-2	>= 0.1 - < 0.2 %	H242, H226, H302, H311, H330, H314, H318, H317, H341, H411

**For the full text of the H-Statements mentioned in this Section, see Section 16.

4. FIRST AID MEASURES

Inhalation:
If inhaled, remove victim to fresh air.

Skin:
In case of contact, immediately flush skin with soap and plenty of water. Remove contaminated clothing and shoes. Get medical attention if symptoms occur. Wash clothing before reuse. Thoroughly clean shoes before reuse.

Eyes:
Immediately flush eye(s) with plenty of water.

Ingestion:
If swallowed, DO NOT induce vomiting. Call a physician or Poison Control Center immediately. If vomiting occurs, have person lean forward. Never give anything by mouth to an unconscious person.

5. FIREFIGHTING MEASURES

Extinguishing media (suitable):
Water spray, Foam, Dry chemical

Protective equipment:
Fire fighters and others who may be exposed to products of combustion should wear full fire fighting turn out gear (full Bunker Gear) and self-contained breathing apparatus (pressure demand / NIOSH approved or equivalent).

Further firefighting advice:
Fight fire with large amounts of water from a safe distance.
Cool closed containers exposed to fire with water spray.
Closed containers of this material may explode when subjected to heat from surrounding fire.
After a fire, wait until the material has cooled to room temperature before initiating clean-up activities.
Do not allow run-off from fire fighting to enter drains or water courses.
Fire fighting equipment should be thoroughly decontaminated after use.

Fire and explosion hazards:
Contact with incompatible materials or exposure to temperatures exceeding the SADT may result in a self accelerating decomposition reaction with release of flammable vapors which may autoignite.
When burned, the following hazardous products of combustion can occur:
Carbon oxides
Hazardous organic compounds

6. ACCIDENTAL RELEASE MEASURES

Personal precautions, Emergency procedures, Methods and materials for containment/clean-up:
Prevent further leakage or spillage if you can do so without risk. Evacuate area of all unnecessary personnel. Ventilate the area. Eliminate all ignition sources. Avoid generation of vapors. DO NOT USE peat moss. Sweep or scoop up using non-sparking tools and place into suitable properly labeled containers for prompt disposal. The sweepings should be wetted down further with water. Avoid dispersal of spilled material and runoff and contact with soil, waterways, drains and sewers. Consult a regulatory specialist to determine appropriate state or local reporting requirements, for assistance in waste characterization and/or hazardous waste disposal and other requirements listed in pertinent environmental permits.

Protective equipment:
Appropriate personal protective equipment is set forth in Section 8.

7. HANDLING AND STORAGE

Handling

General information on handling:
Contact with materials to avoid or exposure to temperatures exceeding the SADT may result in a self-accelerating decomposition reaction with release of flammable vapors which may autoignite.
Avoid breathing vapor or mist.
Do not taste or swallow.
Avoid prolonged or repeated contact with skin.
Keep away from heat, sparks and flames.
When using do not eat, drink or smoke.
Use only with adequate ventilation.
Wash thoroughly after handling.
Prevent product contamination.
Keep container tightly closed and away from combustible materials.
Keep only in the original container.
Container hazardous when empty.
Do not reuse container as it may retain hazardous product residue.
Improper disposal or reuse of this container may be dangerous and/or illegal.
Emptied container retains vapor and product residue.
Observe all labeled safeguards until container is cleaned, reconditioned or destroyed.

Storage

General information on storage conditions:
Store in closed containers, in a secure area to prevent container damage and subsequent spillage. Outside or detached storage is preferred. Store out of direct sunlight in a cool well-ventilated place. Store in original container. Store away from combustibles and materials to avoid. Refer also to National Fire Protection Association (NFPA) Code 400, Hazardous Materials Code.

Storage stability – Remarks:
Follow the recommended storage temperatures provided in this Section in order to maintain stability and oxygen content.

Storage incompatibility – General:
Store separate from:

Strong acids

Strong bases

Strong oxidizing agents

Reducing agents

Accelerators

Friedel - Crafts reaction catalyst

Iron

Copper

Brass

For all Organic Peroxides, compatible materials of contact are stainless steel 304 or 316 (preferred), high-density polyethylene (HDPE), polytetrafluoroethylene or glass linings.

Temperature tolerance – Do not store above:
86 °F (30 °C)

8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Airborne Exposure Guidelines:

White mineral oil (petroleum) (8042-47-5)

US. ACGIH Threshold Limit Values

Form:	Inhalable fraction.
Time weighted average	5 mg/m3

US. OSHA Table Z-1 Limits for Air Contaminants (29 CFR 1910.1000)

Form:	Mist
PEL:	5 mg/m3

Only those components with exposure limits are printed in this section. Limits with skin contact designation above have skin contact effect. Air sampling alone is insufficient to accurately quantitate exposure. Measures to prevent significant cutaneous absorption may be required. Limits with a sensitizer designation above mean that exposure to this material may cause allergic reactions.

Engineering controls:
Investigate engineering techniques to reduce exposures below airborne exposure limits or to otherwise reduce

exposures. Provide ventilation if necessary to minimize exposures or to control exposure levels to below airborne exposure limits (if applicable see above).If practical, use local mechanical exhaust ventilation at sources of air contamination such as open process equipment.

Consult ACGIH ventilation manual or NFPA Standard 91 for design of exhaust systems.

Respiratory protection:
Avoid breathing vapor or mist. Where airborne exposure is likely or airborne exposure limits are exceeded (if applicable, see above), use NIOSH approved respiratory protection equipment appropriate to the material and/or its components. Full facepiece equipment is recommended and, if used, replaces need for face shield and/or chemical goggles. Consult respirator manufacturer to determine appropriate type equipment for a given application. Observe respirator use limitations specified by NIOSH or the manufacturer. For emergency and other conditions where there may be a potential for significant exposure or where exposure limit may be significantly exceeded, use an approved full face positive-pressure, self-contained breathing apparatus or positive-pressure airline with auxiliary self-contained air supply. Respiratory protection programs must comply with 29 CFR § 1910.134.

Skin protection:
Wear appropriate chemical resistant protective clothing and chemical resistant gloves to prevent skin contact. Consult glove manufacturer to determine appropriate type glove material for given application. Wear chemical goggles, a face shield, and chemical resistant clothing such as a rubber apron when splashing may occur. Rinse immediately if skin is contaminated. Remove contaminated clothing immediately and wash before reuse. Clean protective equipment before reuse. Provide a safety shower at any location where skin contact can occur. Wash thoroughly after handling.

Eye protection:
Where there is potential for eye contact, wear a face shield, chemical goggles, and have eye flushing equipment immediately available.

9. PHYSICAL AND CHEMICAL PROPERTIES

Color:	colourless
Physical state:	liquid
Odor:	Slightly aromatic
Odor threshold:	No data available.
Flash point	208 °F (98 °C)
Auto-ignition temperature:	No data available
Lower flammable limit (LFL):	No data available
Upper flammable limit (UFL):	No data available
pH:	No data available
Density:	900 g/cm3

Vapor pressure:	slight
Vapor density:	No data available
Boiling point/boiling range:	Decomposes on heating. Rate of decomposition increases with rising temperature.
Melting point/range:	No data available.
Freezing point:	No data available.
Evaporation rate:	No data available
Solubility in water:	insoluble
Solubility in other solvents: [qualitative and quantative]	Soluble in most organic solvents
Refractive index:	1.46 68 °F (20 °C)
Viscosity, kinematic:	33 mm2/s 68 °F (20 °C)
	15 mm2/s 104 °F (40 °C)
Viscosity, dynamic:	No data available.
Oil/water partition coefficient:	6.5 77 °F (25 °C) (Method: OECD Test Guideline 117)
Self-Accelerating Decomposition Temperature (SADT):	149 °F (65 °C) (Method: BAM (Berlin))
Thermal decomposition	248 °F (120 °C)
Active oxygen content:	6.1 %
Flammability:	See GHS Classification in Section 2

10. STABILITY AND REACTIVITY

Stability:
This material is chemically unstable and should only be handled under specified conditions. See HANDLING AND STORAGE section of this SDS for specified conditions.

Hazardous reactions:
Hazardous polymerization does not occur.

Materials to avoid:
Strong acids
Strong bases
Strong oxidizing agents
Reducing agents
Accelerators

Friedel - Crafts reaction catalyst
Brass
Copper
Iron
For all Organic Peroxides, compatible materials of contact are stainless steel 304 or 316 (preferred), high-density polyethylene (HDPE), polytetrafluoroethylene or glass linings.

Conditions / hazards to avoid:
See HANDLING AND STORAGE section of this SDS for specified conditions. SADT - Self Accelerating Decomposition Temperature. Lowest temperature at which the tested package size will undergo a self-accelerating decomposition reaction. This reaction will generate flammable vapors which may autoignite. The length of time to generate a decomposition reaction, after the SADT has been reached or exceeded, is dependent upon how much the SADT has been exceeded and the length of time needed for the reaction exotherm (heat spike from increasing decomposition rate) to initiate a rapid decomposition reaction. Typically, SADT is inversely proportional to package size. Larger packages will have a lower SADT due to smaller ratio to heat transfer area to volume of product.

Hazardous decomposition products:

Temperatures at or above SADT can result in the release of hazardous decomposition products which are flammable and may autoignite.
Thermal decomposition giving flammable and toxic products :
Carbon oxides
Hazardous organic compounds

11. TOXICOLOGICAL INFORMATION

Data on this material and/or its components are summarized below.

Data for LUPEROX® 331MO50

Acute toxicity

Dermal:
Acute toxicity estimate > 5,000 mg/kg.

Inhalation:
4 h Acute toxicity estimate > 40 mg/l. (vapor)

Data for White mineral oil (petroleum) (8042-47-5)

Acute toxicity

Oral:
No deaths occurred. (rat) LD0 > 5,000 mg/kg.

Skin Irritation:
Not irritating. (rabbit) Irritation Index: 0/8. (24 h) (occluded exposure)

Eye Irritation:
Causes mild eye irritation. (rabbit) Irritation Index: 0.2 - 0.3/110.

Skin Sensitization:
Not a sensitizer. Guinea pig maximization test. (guinea pig) No skin allergy was observed

Not a sensitizer. Buehler method. (guinea pig) No skin allergy was observed

Repeated dose toxicity
3 months dermal route administration to rat / signs: Local irritation

Repeated Dietary administration to rat / affected organ(s): liver, lymph node, spleen / signs: changes in organ structure or function

Repeated Dietary administration to dog / No adverse effects reported.

Repeated Inhalation administration to rat / affected organ(s): lung / signs: changes in organ weights, changes in organ structure or function

Carcinogenicity
Chronic Dermal administration to mouse / signs: No increase in tumor incidence was reported.

Chronic Inhalation administration to various animal species / signs: No adverse effects reported.

Genotoxicity

Assessment in Vitro:
No genetic changes were observed in laboratory tests using: animal cells, bacteria

Genotoxicity

Assessment in Vivo:
No genetic changes were observed in laboratory tests using: mice

Developmental toxicity

Exposure during pregnancy. Oral (rat) / No birth defects were observed.

Reproductive effects
Reproduction test. Oral (rat) / No toxicity to reproduction.

Other information
The information presented is from representative materials with this Chemical Abstract Service (CAS) Registry number. The results vary depending on the size and composition of the test substance.

Human experience
Inhalation:
Upper respiratory tract: chemical pneumonitis, phlegm, coughing, wheezing. (mist)

Human experience
Skin contact:
Skin: dermatitis, acne.

Data for Peroxide, cyclohexylidenebis[(1,1-dimethylethyl) (3006-86-8)

Acute toxicity

Oral:

Practically nontoxic. (rat) LD50 = 16,653 mg/kg. (65 %)

Skin Irritation:
Causes mild skin irritation. (rabbit) Irritation Index: 1,2/8,0. (24 h) (65 %)

Repeated dose toxicity
Repeated exposure oral administration to rat / affected organ(s): kidney / reduced body weight

Genotoxicity

Assessment in Vitro:
No genetic changes were observed in laboratory tests using: bacteria, human cells, animal cells

Reproductive effects
Reproductive/Developmental Effects Screening Assay. oral (rat) / No effects on fertility

Data for Hydroperoxide, 1,1-dimethylethyl (75-91-2)

Acute toxicity

Oral:
Harmful if swallowed. (Rat) LD50 = 406 mg/kg. (100 %)

Harmful if swallowed. (Rat) LD50 = 810 mg/kg. (70 %) (as aqueous solution)

Skin Irritation:
Causes severe skin burns. (Rabbit) (24 h) (70 %) (occluded exposure, aqueous solution)

Causes mild skin irritation. (Guinea pig) (6 h) (5 %) (aqueous solution)

Eye Irritation:
Causes serious eye damage. (Rabbit) (70 %) (aqueous solution)

Skin Sensitization:
May cause an allergic skin reaction. Guinea pig maximization test. (Guinea pig) Skin allergy was observed. (Strong sensitizer)

Repeated dose toxicity
Repeated inhalation administration to Rat / affected organ(s): nose / signs: changes in body weight, irritation / (vapor)

Repeated oral administration to Rat / affected organ(s): stomach / signs: severe irritation

Genotoxicity

Assessment in Vitro:
Genetic changes were observed in laboratory tests using: bacteria, animal cells

Genotoxicity

Assessment in Vivo:
Both positive and negative responses for genetic changes were observed in laboratory tests using: mice

No genetic changes were observed in laboratory tests using: rats

Developmental toxicity

Exposure during pregnancy. oral (Rat) / No birth defects were observed. (at doses that produce effects in mothers)

Reproductive effects
Reproductive/Developmental Effects Screening Assay. oral (Rat) / No toxicity to reproduction.

12. ECOLOGICAL INFORMATION

Chemical Fate and Pathway
Data on this material and/or its components are summarized below.

Data for White mineral oil (petroleum) (8042-47-5)

Biodegradation:
Not readily biodegradable. (28 d) biodegradation 31 %

Octanol Water Partition Coefficient:
log Pow > 6 (calculated)

Data for Peroxide, cyclohexylidenebis[(1,1-dimethylethyl) (3006-86-8)

Biodegradation:
Not readily biodegradable. (Modified Sturm Test, 28 d) biodegradation 5 %

Octanol Water Partition Coefficient:
log Pow > 6.5

Data for Hydroperoxide, 1,1-dimethylethyl (75-91-2)

Biodegradation:
Not readily biodegradable. (28 d) biodegradation 0 %

Octanol Water Partition Coefficient:
log Pow = 0.846 (Not expected to bioaccumulate.)

Photodegradation:
Air reaction with OH radicals Half-life direct photolysis: = 5.3 d

Ecotoxicology
Data on this material and/or its components are summarized below.

Data for White mineral oil (petroleum) (8042-47-5)

Aquatic toxicity data:
No effect up to the limit of solubility. Lepomis macrochirus (Bluegill sunfish) 96 h > 10,000 mg/l

Aquatic invertebrates:
No effect up to the limit of solubility. Daphnia magna (Water flea) 48 h (Immobilization)

Algae:
No effect up to the limit of solubility. Pseudokirchneriella subcapitata (green algae) 72 h (growth rate inhibition)

Chronic toxicity to aquatic invertebrates:
No effect up to the limit of solubility. Daphnia magna (Water flea) 21 d (Reproduction inhibition)

Chronic toxicity to aquatic plants:
No effect up to the limit of solubility. Pseudokirchneriella subcapitata (green algae) 96 h (growth rate inhibition)

Data for Peroxide, cyclohexylidenebis[(1,1-dimethylethyl) (3006-86-8)

Aquatic toxicity data:
No effect up to the limit of solubility. Danio rerio (zebra fish) 96 h LC50 > 0.64 mg/l

Aquatic invertebrates:
No effect up to the limit of solubility. Daphnia (water flea) 48 h EC50 > 0.6 mg/l

Algae:
No effect up to the limit of solubility. Pseudokirchneriella subcapitata (green algae) 72 h EC50 > 0.5 mg/l

Microorganisms:
No effect up to the limit of solubility. Activated sludge 3 h EC50 > 20 mg/l

Data for Hydroperoxide, 1,1-dimethylethyl (75-91-2)

Aquatic toxicity data:
Harmful. Pimephales promelas (fathead minnow) 48 h LC50 = 29.61 mg/l
Harmful. Poecilia reticulata (guppy) 96 h LC50 = 56.9 mg/l

Aquatic invertebrates:
Harmful. Daphnia magna (Water flea) 48 h EC50 = 14.1 mg/l

Algae:
Toxic. Algae 72 h EC50 = 1.5 mg/l

Microorganisms:
Slightly toxic. Respiration inhibition / Activated sludge 0.5 h EC50 = 17 mg/l

13. DISPOSAL CONSIDERATIONS

Waste disposal:
Dilution followed by incineration is the preferred method. Dilution ratio of 10:1 in a clean, compatible, combustible solvent (i.e., Fuel Oil #2, mineral oil) will reduce reactivity hazard during incineration and transportation. Dispose of in accordance with federal, state and local regulations. Consult a regulatory specialist to determine appropriate state or local reporting requirements, for assistance in waste characterization and/or hazardous waste disposal and other requirements listed in pertinent environmental permits. Note: Chemical additions to, processing of, or otherwise altering this material may make this waste management information incomplete, inaccurate, or otherwise inappropriate. Furthermore, state and local waste disposal requirements may be more restrictive or otherwise different from federal laws and regulations.

Take appropriate measures to prevent release to the environment.

14. TRANSPORT INFORMATION

US Department of Transportation (DOT)

UN Number	:	3105
Proper shipping name	:	Organic peroxide type D, liquid
Technical name	:	(1,1-Di-(tert-butylperoxy) cyclohexane, >42-52%)
Class	:	5.2
Packaging group	:	II
Marine pollutant	:	no

International Maritime Dangerous Goods Code (IMDG)

UN Number	:	3105
Proper shipping name	:	ORGANIC PEROXIDE TYPE D, LIQUID
Technical name	:	(1,1-DI-(tert-BUTYLPEROXY) CYCLOHEXANE, >42-52%)
Class	:	5.2
Marine pollutant	:	no
Flash point	:	208 °F (98 °C)

15. REGULATORY INFORMATION

Chemical Inventory Status

EU. EINECS	EINECS	Conforms to
United States TSCA Inventory	TSCA	The components of this product are all on the TSCA Inventory.
Canadian Domestic Substances List (DSL)	DSL	All components of this product are on the Canadian DSL
China. Inventory of Existing Chemical Substances in China (IECSC)	IECSC (CN)	Conforms to
Japan. ENCS - Existing and New Chemical Substances Inventory	ENCS (JP)	Conforms to
Japan. ISHL - Inventory of Chemical Substances	ISHL (JP)	Conforms to
Korea. Korean Existing Chemicals Inventory (KECI)	KECI (KR)	Conforms to
Philippines Inventory of Chemicals and Chemical Substances (PICCS)	PICCS (PH)	Conforms to
Australia Inventory of Chemical Substances (AICS)	AICS	Conforms to

United States – Federal Regulations

SARA Title III – Section 302 Extremely Hazardous Chemicals:

The components in this product are either not SARA Section 302 regulated or regulated but present in negligible concentrations.

SARA Title III - Section 311/312 Hazard Categories:
Acute Health Hazard, Reactivity Hazard

SARA Title III – Section 313 Toxic Chemicals:
This material does not contain any chemical components with known CAS numbers that exceed the threshold (De Minimis) reporting levels established by SARA Title III, Section 313.

Comprehensive Environmental Response, Compensation, and Liability Act (CERCLA) - Reportable Quantity (RQ):

Chemical Name	CAS-No.	Reportable quantity
Hydroperoxide, 1,1-dimethylethyl	75-91-2	100 lbs

United States – State Regulations

New Jersey Right to Know

Chemical Name	CAS-No.
White mineral oil (petroleum)	8042-47-5

New Jersey Right to Know – Special Health Hazard Substance(s)

Chemical Name	CAS-No.
White mineral oil (petroleum)	8042-47-5

Pennsylvania Right to Know

Chemical Name	CAS-No.
White mineral oil (petroleum)	8042-47-5
Peroxide, cyclohexylidenebis[(1,1-dimethylethyl)	3006-86-8

California Prop. 65
This product does not contain any chemicals known to the State of California to cause cancer, birth defects, or any other reproductive defects.

16. OTHER INFORMATION

Full text of H-Statements referred to under sections 2 and 3.

H226 Flammable liquid and vapour.
H241 Heating may cause a fire or explosion.
H242 Heating may cause a fire.
H302 Harmful if swallowed.
H311 Toxic in contact with skin.
H314 Causes severe skin burns and eye damage.
H317 May cause an allergic skin reaction.
H318 Causes serious eye damage.
H330 Fatal if inhaled.
H341 Suspected of causing genetic defects.
H411 Toxic to aquatic life with long lasting effects.
H413 May cause long lasting harmful effects to aquatic life.

Miscellaneous:

Other information:	Refer to National Fire Protection Association (NFPA) Codes 30, 70, 77, and 497 and OSHA 29 CFR 1910.106, for safe handling.

Latest Revision(s):

Reference number:	000000098132
Date of Revision:	02/16/2016
Date Printed:	02/16/2016

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Arkema has implemented a Medical Policy regarding the use of Arkema products in Medical Devices applications that are in contact with the body or circulating bodily fluids (http://www.arkema.com/en/social-responsibility/responsible-product-management/medical-device-policy/index.html) Arkema has designated Medical grades to be used for such Medical Device applications. Products that have not been designated as Medical grades are not authorized by Arkema for use in Medical Device applications that are in contact with the body or circulating bodily fluids. In addition, Arkema strictly prohibits the use of any Arkema products in Medical Device applications that are implanted in the body or in contact with bodily fluids or tissues for greater than 30 days. The Arkema trademarks and the Arkema name shall not be used in conjunction with customers' medical devices, including without limitation, permanent or temporary implantable devices , and customers shall not represent to anyone else, that Arkema allows, endorses or permits the use of Arkema products in such medical devices.
It is the sole responsibility of the manufacturer of the medical device to determine the suitability (including biocompatibility) of all raw materials, products and components, including any medical grade Arkema products, in order to ensure that the final end-use product is safe for its end use; performs or functions as intended; and complies with all applicable legal and regulatory requirements (FDA or other national drug agencies) It is the sole responsibility of the manufacturer of the medical device to conduct all necessary tests and inspections and to evaluate the medical device under actual end-use requirements and to adequately advise and warn purchasers, users, and/or learned intermediaries (such as physicians) of pertinent risks and fulfill any postmarket surveillance

obligations. Any decision regarding the appropriateness of a particular Arkema material in a particular medical device should be based on the judgment of the manufacturer, seller, the competent authority, and the treating physician.